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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,530	10/10/2001	Jon G. Wilkes	4239-60896	9402
36218	7590	01/12/2004	EXAMINER	
KLARQUIST SPARKMAN, LLP 121 S.W. SALMON STREET, SUITE #1600 ONE WORLD TRADE CENTER PORTLAND, OR 97204-2988			LY, CHEYNE D	
ART UNIT		PAPER NUMBER		
1631				

DATE MAILED: 01/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.	09/975,530	Applicant(s)	WILKES ET AL.
Examiner	Cheyne D Ly	Art Unit	1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1) Responsive to communication(s) filed on 30 October 2003.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

4) Claim(s) 20-47 and 67-80 is/are pending in the application.

4a) Of the above claim(s) 33-47, 67, 68 and 72-80 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 20-32 and 69-71 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) 20-47 and 67-80 are subject to restriction and/or election requirement.

### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \*    c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) The translation of the foreign language provisional application has been received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.

4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

**DETAILED ACTION**

1. Applicants' arguments, filed October 30, 2003, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.
2. The new title has been accepted.
3. The addition of new claims 71-80 has been acknowledged.
4. Claims 21 and 31 have been withdrawn by Applicant, which is acknowledged. It is noted that claims 22 and 31 have been objected in the previous Office Action, mailed June 26, 2003. Further, the basis for said objection is that claims 22 and 31 are directed to non-elected species; therefore, the non-elected species have been withdrawn from examination. It is assumed that applicants have inadvertently withdrawn claim 31 due to the objection being not clear. Further, the withdrawal of claim 21 is a response to the above objection of claim 22. It is further assumed that the withdrawal of claim 21 has been a typographical error. The withdrawal of claims 21 and 31 has been rescinded.
5. Claims 33-47, 67, 68, and 72-80 have been withdrawn due to being directed to non-elected subject matter.
6. Specific to claims 72-80, the claims have been withdrawn due to the claimed method being distinct from the elected group. The method of claims 72-80 is directed to a computer implemented method for analyzing fingerprint spectra data for compensating for environmentally induced drift without requiring the step of culturing microorganisms. The

elected invention requires the step culturing microorganisms; therefore, it is distinct from the claimed invention of claims 72-80.

7. Claims 20-32 and 69-71 are examined on the merits.

### **CLAIM REJECTIONS - 35 USC § 103**

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 20-32, and 69-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodacre et al. (1996) taken with Sockalingum et al. (1998).

11. This rejection is maintained with respect to claims 20-32, 69, and 70, as recited in the previous office action, mailed June 26, 2003. The instant rejection has been extended to claim 71.

12. This rejection is necessitated by Applicants' amendments.

### **RESPONSE TO APPLICANT'S ARGUMENT**

13. Applicants argue that the previous Office Action does not present a *prima facie* case of obviousness for claims 20-32, 69, and 70 due to the references, Goodacre et al., Sockalingum et al., and Canto et al., alone or combination, do not disclose every limitation of the claimed invention as directed to claims 20-32, 69, and 70. Applicants specifically argue that Goodacre et al. "reference teaches compensation for instrumental drift between measurements when the environmental conditions that metabolically affect the organism are maintained the same." "Sockalingum [et al.] teaches only that "by standardizing growth conditions and instrumental parameters, IR spectra of intact bacterial cells can be reproducibly measured." "One of ordinary skill in the art would not be motivated to make a combination of Goodacre et al., Sockalingum et al., [and Canto et al.] to arrive at a method for correcting for drift due to changes in environmental factors." Applicants' arguments and pointed to citations have been duly considered and found to be unpersuasive as discussed below.

14. Applicants' argument as directed Canto et al. has been made moot due to the withdrawal of claim 45.

15. Specific to Applicants' argument of lack of motivation to combine the disclosures of Goodacre et al. and Sockalingum et al., Goodacre et al. discloses "a continuing need for more rapid, precise, and accurate analyzes of the (bio)chemical composition of (micro)biological systems, both within biotechnology and for the identification of potentially pathogenic organisms" (page 271, column 1, lines 1-4), which is sufficient to motivate one of ordinary to

further improve on the method of Goodacre et al. Sockalingum et al. discloses by standardizing growth conditions and instrumental parameters (spectral drift), IR spectra of intact bacterial cells can be reproducibly measured for rapid screening of microorganisms (page 268, column 1, lines 20-36). Therefore, one of ordinary skill in the art would be motivated to combine the teaching of Goodacre et al. and Sockalingum et al. to arrive at a method for correcting for drift due to changes in environmental factors.

16. Specific to Applicant's argument that Goodacre et al. and Sockalingum et al., alone or combination, do not disclose the limitation of compensating for instrumental drift between measurements when the environmental conditions are different. Applicant's argument has been fully considered and found to be unpersuasive as discussed below. As recited in the previous Office Action (page 6, ¶ 20), mailed June 26, 2003, the method of Sockalingum et al. comprises culturing *E. coli* for 18 hours at 35<sup>0</sup> C and *P. aeruginosa* for 16 hours at 37<sup>0</sup> C, a library of media of the same batch wherein the media may differ in specific antibiotics and spectra similarity is determined by hierarchical grouping or cluster analysis (page 262, Materials and Methods; page 263, lines 7-9; and Figures 3 and 4). Therefore, Sockalingum et al. in combination with Goodacre et al. sufficiently disclose the limitation of compensating for instrumental drift between measurements when the environmental conditions are different as defined by the pointed to support in the specification.

17. The disclosures of Goodacre et al. and Sockalingum et al. provide the overwhelming need for one of skill in the art at the of the instant invention to improve on the methods of Goodacre et al. and Sockalingum et al. to arrive at a method for correcting for drift due to

changes in environmental factors. Therefore, the combination of references of Goodacre et al. and Sockalingum et al. as a whole discloses the limitations of the instant invention.

18. Goodacre et al. discloses a method for correcting pyrolysis mass spectrometry drift using artificial neural networks (Abstract etc.). The method of Goodacre et al. comprises culturing microorganisms and measuring fingerprint spectrum of the said microorganisms (page 275, column 1, lines 33-67 to column 2, lines 1-19). PyMS has been used routinely to identify microorganisms and combined with ANNs to quantify biological systems (e.g. metabolites of interest) (page 272, column 2, lines 19-21) and the drift correction is performed by taking the difference of two different spectra and transforms the said spectra data (page 276, column 1, lines 11-21). The method is performed using the Unscrambler II Version 4.0 program in MS-DOS 6.2 on a PC (page 273, lines 35-39), as in claims 20, 22, 32, and 69.
19. The method of Goodacre et al. is directed to bacteria *Bacillus subtilis*, *Escherichia coli*, and *staphylococcus aureus*, wherein microorganisms are analyzed in a single batch and different strains (page 272, column 1, lines 1-8 and 25-29), as in instant claims 25-28.
20. The method of Goodacre et al. is an improvement the identification approach wherein the interpretation of complex principal components analysis and canonical variates analysis plots are used (page 272, column 1, lines 18-23), as in instant claims 29 and 30.
21. However, Goodacre et al. does not disclose the limitations of the environmental factor being the difference in temperature, library of culture media, similarity between expected fingerprint spectra and the expected spectra is added to a database.

22. Sockalingum et al. discloses a method for rapid screening of microorganisms based on FT-IR spectroscopy (Abstract et al.). The data generated from the said method is kept in a data bank for the rapid identification and characterization of different species (page 261, column 2, line 19 to page 262, column 1, lines 1-4), as in claim 70.
23. The method of Sockalingum et al. comprise culturing *E. coli* for 18 hours at 35<sup>0</sup> C and *P. aeruginosa* for 16 hours at 37<sup>0</sup> C, a library of media of the same batch wherein the media may differ in specific antibiotics and spectra similarity is determined by hierarchical grouping or cluster analysis (page 262, Materials and Methods; page 263, lines 7-9; and Figures 3 and 4), as in claims 21, 23, 24, 31, and 71.

### **CONCLUSION**

24. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
25. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

26. This application contains claims 33-47, 67, 68, and 72-80 are drawn to an invention nonelected with traverse in the previous Office Action, mailed June 26, 2003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

27. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 872-9306.

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

29. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

30. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly  
1/7/04

*Ardin H. Marschel*  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER